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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,878

09/27/2005

Kenji Yasuda

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EXAMINER

HOBBS, MICHAEL L

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

08/10/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/525,878	Applicant(s) YASUDA, KENJI	
	Examiner MICHAEL HOBBS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-11 and 15-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-11 and 15-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed on 06/30/2010 has been considered and entered for the record.

Preliminary Remarks

2. The following initial remarks regarding the Office Action mailed 03/03/2010 are made in light of applicant's amendment and remarks filed on 06/30/2010:

The translation of the Foreign priority document filed on 06/30/2010 overcomes the 35 USC 103(a) rejection in paragraph 5 of the previous Office Action.

3. Claims 6-11 and 15-25 are pending further examination upon the merits.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
- 5.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1797

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 6-9, 11 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jimbo et al. (IEEE Transactions on Biomedical Engineering. Vol. 40 no. 8 August 1993) in view of Hänni et al. (US 6,689,594 B1) (will be referred to as Hänni) and in further view of Sugihara et al. (US 5,563,067 A) (will be referred to as '067).

9. Jimbo discloses a substrate for multi-site monitoring of electrical signals using multi-electrode array for monitoring the growth of neural cells. For claim 6, Jimbo discloses a substrate with an electrode array for monitoring electrical signals or measuring potential from neurites (section II Experimental Method, sub-section A *Fabrication of Electrode Array Substrates*). The substrates are constructed from a glass substrate with ITO (indium tin oxide) electrodes and with wells formed of a double layer of Al_2O_3 and polyimide (section II Experimental Method, sub-section A *Fabrication of Electrode Array Substrates*). The wells form a wall around each measuring site and these walls are "discontinuous" since each site is connected by a conduit (Fig. 2). Finally, Jimbo discloses placing a coating of poly-L-lysine and laminin (section II

Art Unit: 1797

Experimental Method, sub-section B *Cell Culture* lines 1-6 of the first paragraph) in order to promote cell adhesion.

10. However, Jimbo is silent regarding an optically transparent membrane over the regions.

11. Hänni discloses a device for organic cell culture for testing the electrophysiological activity of nerve cells. For claim 6, Hänni discloses that a transparent porous membrane (membrane 16) is placed on the support structure (support 11) in order to cover an opening (opening 15; col. 3 lines 9-11). Therefore, it would be obvious to one of ordinary skill in the art to employ the membrane as suggested by Hänni in order to retain the cells within the wells of Jimbo. The suggestion for doing so at the time would have been in order to provide a cover for the opening (col. 3 lines 11-12).

12. Both Jimbo and Hänni differ from the instant claim regarding the coating being formed of collagen.

13. '067 discloses a cell potential apparatus that includes using an integrated cell holding instrument with a plurality of microelectrodes on a substrate and a connection means for providing an electrical signal to the electrode (col. 1 lines 60-64). Nerve cells are cultured on the integrated holding cell and the potential change accompanied by the activities of the nerve cells were measured by the instrument of '067 (col. 8 line 64 - col. 9 line 3). For claim 6, '067 discloses coating the electrodes with a collagen gel (col. 9 lines 42-44) and a cerebral cortex section from a rat was placed over the microelectrode area that was coated with the gel. '067 further discloses that the electrodes were

Art Unit: 1797

covered with a collagen gel in order to enhance the adhesive property of each planar electrode with the cells (col. 9 lines 43-45).

14. It should be noted that the combined teachings of Jimbo and Hänni disclose the claimed invention expect for coating the electrodes with collagen. In this case, the applied reference of Jimbo uses laminin to promote cell adhesion between the electrodes and nerve cells. '067 demonstrates that collagen was a known cell attachment surface for nerve cells and that the skilled artisan would have been aware of the properties of either laminin or collagen as a cell attachment surface at the time of the instant application. Therefore, following rationale B of *KSR*, 550 U.S. at ____, 82 USPQ2d at 1395, it would have been obvious for one of ordinary skill in the art to substitute the collagen gel suggested by '067 for the laminin of Jimbo and Hänni in order to have a cell attachment surface. The suggestion for doing this at the time would have been in order to have a surface with enhanced cell adhesion properties.

15. For claim 7, Jimbo discloses an electrode array as discussed above that is fully capable of measuring the potential change of a nerve cell on the same electrode and for claims 8,15, the electrodes are made of ITO which is a transparent conductive material (section II Experimental Method, sub-section A *Fabrication of Electrode Array Substrates*). For claims 9 and 16-18, Jimbo further discloses at least three electrodes within the array that are fully capable of carrying out measurements independently and for claim 11 the number of regions is at least three or greater as shown in Figure 3.

16. For claims 10 and 19-25, Jimbo and Hänni are silent about the walls being made of a photo-curable resin.

17. Claims 10 and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jimbo et al. (IEEE Transactions on Biomedical Engineering. Vol. 40 no. 8 August 1993) in view of Hänni et al. (US 6,689,594 B1) (will be referred to as Hänni) and Sugihara et al. (US 5,563,067 A) (will be referred to as '067) as applied above and in further view of Sugihara et al. (WO 99/34202) (will be referred to as '202).

18. It should be noted that in the previous Office Action, claim 10 was clearly rejected as it was rejected in the body of the rejection and although not included in the 103 statement, this was a minor oversight which has been corrected in this action.

19. With regards to claims 10 and 19-25 Jimbo, Hänni and '067 differ from the instant claims regarding how the substrates are made.

20. With regards to claims 10 and 19-25, '202 (Sugihara) further discloses that the electrode sites or compartments are formed by applying the ITO film to a glass substrate and the conductive pattern is formed by photo-resist and etching (page 10 lines 15-16). The insulating film is formed by a negative photosensitive polyimide film or photo-curable resin (page 10 lines 16-17). Furthermore, '202 demonstrates that using a photo-curable material to form a culture chamber for cells was known at the time of the instant application. Therefore, following rationale C of *KSR*, 550 U.S. at ____, 82 USPQ2d at 1396, it would have been obvious to one of ordinary skill in the art to employ the photo-curable resin suggested by Sugihara within the culture chamber of Jimbo Hänni and '667 in order to construct the well walls of the array.

Art Unit: 1797

21. Applicant is reminded that process steps in an apparatus are not accorded patentable weight. "The patentability of a product does not depend on its method of production". If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)." Furthermore, the processing steps do not structurally define the instant application over the prior art since the claimed processing steps do not impart a distinctive structural characteristic to the final product.

Response to Arguments

Applicant's arguments with respect to claims 6-9 and 15-18 have been considered but are moot in view of the new ground(s) of rejection.

22. Applicant argues that the currently applied references of Jimbo, Hänni and Sugihara do not render the claim obvious since the applied references do not disclose a microelectrode coated with collagen. This deficiency within the references has been corrected by the newly applied reference of Sugihara (US 5,563,067).

23. With regards to applicant's clarification regarding the rejection of claim 10, this has been clarified above, but claim 10 was addressed in paragraph 22 of the previous Office Action.

24. Therefore, the claims stand rejected.

Conclusion

25. No claims are allowed.
26. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/M. H./
Examiner, Art Unit 1797